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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,047	09/23/2002	Manuel Fresno Escudero	34909-PCT USA 069277.0108	8670
21003	7590	02/09/2005	EXAMINER	
BAKER & BOTTS 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			PAK, YONG D	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/031,047	Applicant(s) ESCUDERO ET AL.	
	Examiner Yong D Pak	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10,12-14,16-24 and 26-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10,12-14,16-24 and 26-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The amendment filed on November 24, 2004, amending claims 10, 14, 18 and 21, canceling claims 11, 15 and 25 and adding claims 26-30, has been entered.

Claims 10, 12-14, 16-24 and 26-30 are pending and are under consideration.

Response to Arguments

Applicant's amendment and arguments filed on November 24, 2004, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 112

Claims 23 and 24 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants argue that deposits of ECACC 9903245 and CECT 5145 have been made under the terms of the Budapest Treaty and therefore has met the requirements of 37 C.F.R. § 1.809. While the deposits have been made, an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his/her signature, and registration number, stating that the specific strain(s) has/have been deposited under

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the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, has not been submitted. See 37 C.F.R. § 1.808. Therefore, the rejection has been maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10, 12, 14, 16, 18, 21-23, 26 and 29-30 and claims 13, 17, 19-20, 24 and 27-28 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10, 12, 14, 16, 18, 21-23, 26 and 29-30 recite the term "gene". The metes and bounds of the phrase in the context of the above claim is not clear to the Examiner. A gene comprises of a coding sequence and introns, exons and regulatory sequences. A perusal of the specification did not provide the Examiner with a specific definition for the above phrase. Therefore, it is not clear whether the above term in said claims encompass the intronic and regulatory sequences or is limited to a cDNA. Examiner suggests replacing the above term with "polynucleotide".

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Claims 10, 12, 14, 16, 18, 21-23, 26 and 29-30 and claims 13, 17, 19-20, 24 and 27-28 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10, 12-13 and 18-22 recite the phrase "human COX-2 sequence". It is not clear to the Examiner what is encompassed by the above phrase, whether it is limited to the coding sequence, non-coding sequence, transcription controlling sequence, 5'UTR or 3'UTR sequences, etc.

Claims 14, 16-17, 26-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14, 16-17, 26-30 recite the phrase "about 1.9 kb of a human cyclooxygenase 2 promoter". The metes and bounds of the phrase in the context of the above claim is not clear to the Examiner, i.e. the start and end of the "about 1.9 kb" of a human COX-2 promoter. It is not clear to the Examiner how one having ordinary skill in the art would choose about 1.9 kb of a human COX-2 promoter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10, 12-14, 16-19, 21-22 and newly submitted claims 26-27 and 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Kutchera et al.

Claims 10, 12-14, 16-19, 21-22, 26-27 and 29-30 are drawn to a polynucleotide comprising or consisting essentially of SEQ ID NO:5 linked to a luciferase gene, vector comprising said polynucleotide and host cell comprising said polynucleotide.

Kutchera et al. (cited on previous form PTO-892 – Proc. Natl. Acad. Sci. USA, Vol. 93, pp. 4816-4820, May 1996) teaches a polynucleotide comprising or consisting essentially of SEQ ID NO:5 of the instant invention. Kutchera et al. teaches a 1963 bp fragment of the promoter region of a human COX-2 promoter (-1840 to +123) which encompasses SEQ ID NO:5 of the instant invention (-1796 to +104) (abstract, pages 4817-4818). The polynucleotide of Kutchera et al. is linked to a Renilla luciferase gene (pages 4817-4818). Kutchera et al. also teach a cell comprising said polynucleotide (pages 4817-4818). Therefore, the teachings of Kutchera et al. anticipate claims 10, 12-14, 16-19, 21-22, 26-27 and 29-30.

Applicants argue that the polynucleotide of Kutchera et al. does not anticipate claims 10, 12-14, 16-19, 21-22 because the polynucleotide of Kutchera et al. is not 100% identical to SEQ ID NO:5 of the instant invention but is a larger sequence (1963 bp) comprising SEQ ID NO:5 (1900 bp). Examiner respectfully disagrees. The claims are drawn to a polynucleotide consisting essentially or comprising of SEQ ID NO:5. A polynucleotide consists essentially of a nucleic acid sequence when such a nucleic acid sequence is present with a few additional nucleic acids. Therefore, the polynucleotide

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of Kutchera et al. consists essentially or comprises of SEQ ID NO:5 and therefore the teachings of Kutchera et al. anticipate claims 10, 12-14, 16-19, 21-22. Therefore, the rejection of claims 10, 12-14, 16-19, 21-22 has been maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 20, 23-24 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kutchera et al. as applied to claims 10, 12-14, 16-19, 21-22, 26-27 and 29-30 above, and further in view of ATCC TIB-152 and GibcoBRL.

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Claims 20, 23-24 and 28 are drawn to Jurkat and *E.coli* DH5 cells comprising a polynucleotide comprising, consisting essentially or consisting of SEQ ID NO:5 linked to a Renilla luciferase gene.

The reference of Kutchera et al., as applied to claims 10, 12-14, 16-19, 21-22, 26-27 and 29-30, teaches a polynucleotide consisting essentially of SEQ ID NO:5 linked to a Renilla luciferase gene, as discussed above. Kutchera et al. also teach that a Renilla luciferase gene linked to the promoter region of human COX can be used to examine transcription levels of the COX gene (page 4818, right column).

The difference between the reference of Kutchera et al. and the instant claims is that the reference of Kutchera et al. does not teach Jurkat or *E. coli* DH5 cells comprising a polynucleotide consisting of SEQ ID NO:5 linked to a luciferase gene or a Jurkat cell consisting essentially of SEQ ID NO:5 linked to a luciferase gene.

However, Kutchera et al. teaches that the promoter region of a human COX-2 gene is well known and its intron-exon boundaries have been mapped (page 4817). One having ordinary skill in the art would have recognized to use the COX-2 promoter fragment of Kutchera et al. or a shorter fragment retaining full functionality upon transfection into cells. Also, expression of genes in Jurkat and *E.coli* DH5 cells are well established in the art. Jurkat and *E.coli* DH5 cells are commercial available, such as through ATCC TIB-152 or GibcoBRL (Catalog 16-1).

Therefore, combining the teachings of the above three references, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made a Jurkat cell comprising the polynucleotide of Kutchera et al. or to make a Jurkat

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cell or E.coli DH5 cell comprising a shorter promoter fragment of Kutchera et al. and to make a biological deposit of said cells. One of ordinary skill in the art would have been motivated to use Jurkat or E.coli DH5 cells since the cells are easy to grow. One of ordinary skill in the art would have been motivated to shorten the COX-2 promoter Kutchera et al., while retaining full functionality, since shorter gene constructs are more advantageous in decreasing steric limitations of vectors and thereby increasing vector infectivity. One of ordinary skill in the art would have had a reasonable expectation of success in making the cells since the cited references teaches successful expression of genes in Jurkat and E.coli DH5 cells. One of ordinary skill in the art would have had a reasonable expectation of success in making a shorter fragment of the promoter taught by Kutchera et al. since Kutchera et al. teaches intron-exon boundaries of COX-2 and since Kutchera et al. teaches how to make fragments of a gene.

Therefore, Kutchera et al. and ATCC TIB-152 render claims 20, 23-24 and 28 prima facie obvious to those skilled in the art.

None of the claims are allowable.

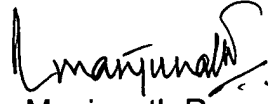
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300 for regular communications and 703-872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Yong D. Pak
Patent Examiner 1652



Manjunath Rao
Primary Examiner 1652